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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,388	01/10/2001	Juha Punnonen	0154.310US	2485

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EXAMINER

EWOLDT, GERALD R

ART UNIT PAPER NUMBER

1644

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/760,388

Applicant(s)

Punnonen et al.

Examiner

G.R. Ewoldt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 8/28/02 and 12/17/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35, 37-42, 44-68, and 70-78 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-35, 37-42, 44-68, and 70-78 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

#### DETAILED ACTION

1. Applicant's Election, filed 8/28/02, and Amendment, filed 12/17/02, are acknowledged.

2. Applicant's election of Group IV, Claims 33-35, 37-41, 52-59, 68, and 70-76, in Paper No. 10, filed 8/28/02, with traverse, is acknowledged. Applicant indicates that the restriction is incomplete as Claims 28 and 29 have not been placed in any group. The Examiner appreciates Applicant's efforts in pointing out the error. Given said error in the previous restriction requirement, said requirement is hereby vacated. A new restriction follows. The Examiner apologizes for any inconvenience or delay.

Regarding Applicant's argument that restriction within a claim is improper, Applicant is advised that when a claim comprises more than one invention, said restriction is indeed proper. In the instant case certain claims, e.g., Claims 1 and 61, encompass inventions that involve methods of recombinant DNA manipulation/gene therapy and methods that do not. Said methods properly belong in different groups. Absent the ability to restrict within a claim when said claim recites multiple patentably distinct inventions, Applicant would need only recite all inventions within a single claim to make all restriction impossible.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-29, 32, and 77, drawn to a method of producing an antigen presenting cell (APC) including a dendritic cell (DC), classified in Class 435, subclass 377.

II. Claims 1-2, 21, 23-24, and 30-31, drawn to a method of producing a recombinant transfected APC, classified in Class 435, subclasses 91.1 and 455.

III. Claims 33-35, 37-41, 52-59, 68, and 70-76, drawn to an APC including a DC, and a vaccine, classified in Class 435, subclass 372.

IV. Claims 42, 44-45, and 60, drawn to a method of inducing an immune response, classified in Class 424, subclasses 278.1.

V. Claims 46-50, drawn to a method of inducing the differentiation of T cells, classified in Class 435, subclass 347.

VI. Claims 51, drawn to T cells, classified in Class 435, subclass 372.3.

VII. Claims 61-67 and 78, drawn to an ex vivo method of inducing an immune response comprising antigen loading, classified in Class 424, subclass 93.71.

VIII. Claims 61-67 and 78, drawn to an ex vivo method of inducing an immune response comprising gene therapy, classified in Class 424, subclass 93.1 and Class 514, subclass 44.

4. Inventions I/II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case the product as claimed can be made by another and materially different process such as by separation from peripheral blood.

5. Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case the product as claimed can be made by another and materially different process such as by separation from peripheral blood.

6. Inventions III and IV/VII/ VIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as in in vitro cell proliferation assays.

7. Inventions I, II, IV, V, VII, and VIII are different methods. Said methods comprise different reagents, e.g., DNA for methods of gene therapy versus antigens for methods of antigen loading, or DCs versus T cells; different method steps, e.g., culturing cells versus transfecting cells; different endpoints, e.g., inducing an immune response versus inducing the differentiation of T cells *in vitro*. Therefore the methods are patentably distinct.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as well as different classifications, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



G.R. Ewoldt, Ph.D.  
Patent Examiner  
Technology Center 1600  
February 22, 2002